



## **ENVIRONMENTAL PROTECTION AGENCY**

**[FRL- 9901-49-ORD; Docket ID No. EPA-HQ-ORD-2013-0680]**

### **Next Generation Risk Assessment: Incorporation of Recent Advances in Molecular, Computational, and Systems Biology [External Review Draft]**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of public comment period and external peer review.

**SUMMARY:** EPA is announcing a 45-day public comment period for the draft document titled, “Next Generation Risk Assessment: Incorporation of Recent Advances in Molecular, Computational, and Systems Biology [External Review Draft]” (EPA/600/R-13/214A). EPA is also announcing that Eastern Research Group, Inc., an EPA contractor, will select a group of external experts to conduct an external peer review of the draft document. The document was prepared by the National Center for Environmental Assessment within EPA’s Office of Research and Development (ORD) as part of the Agency’s Chemical Safety for Sustainability Research Program.

EPA is releasing this draft document for the purposes of public comment and external peer review. This draft document is not final as described in EPA’s information quality

guidelines, and it does not represent and should not be construed to represent Agency policy or views. The public comment period and the external peer review are separate processes that provide opportunities for all interested parties to comment on the document. When finalizing the draft document, EPA intends to consider the external peer reviewer's comments and any public comments that EPA receives in accordance with this notice.

The draft document and EPA's peer review charge are available via the Internet on the NCEA home page under the Recent Additions and the Data and Publications menus at <http://www.epa.gov/ncea>.

**DATES:** The 45-day public comment period begins [INSERT DATE PUBLISHED IN THE FEDERAL REGISTER], and ends [INSERT DATE 45 DAYS AFTER DATE PUBLISHED IN THE FEDERAL REGISTER]. Technical comments should be in writing and must be received by EPA by [INSERT DATE 45 DAYS AFTER DATE PUBLISHED IN THE FEDERAL REGISTER].

**ADDRESSES:** The draft "Next Generation Risk Assessment: Incorporation of Recent Advances in Molecular, Computational, and Systems Biology [External Review Draft]" is available primarily via the Internet on the NCEA home page under the Recent Additions and the Data and Publications menus at <http://www.epa.gov/ncea>. A limited number of paper copies will be available from Ms. Marieka Boyd by phone: 919-541-0031; fax: 919-541-5078; or email: [boyd.marieka@epa.gov](mailto:boyd.marieka@epa.gov). If you are requesting a paper copy, please provide your name, your mailing address, and the document title, "Next Generation Risk Assessment: Incorporation of

Recent Advances in Molecular, Computational, and Systems Biology [External Review Draft]” (EPA/600/R-13/214A) to facilitate processing of your request.

Comments may be submitted electronically via [www.regulations.gov](http://www.regulations.gov), by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions provided in the **SUPPLEMENTARY INFORMATION** section of this notice.

**FOR FURTHER INFORMATION CONTACT:** For information on the public comment period, contact the ORD Docket at the EPA Headquarters Docket Center; telephone: 202-566-1752; facsimile: 202-566-9744; or e-mail: [Docket\\_ORD@epa.gov](mailto:Docket_ORD@epa.gov).

For technical information, contact Dr. Lyle Burgoon, NCEA; telephone: 919-541-7808; facsimile: 919-685-3473; or e-mail: [burgoon.lyle@epa.gov](mailto:burgoon.lyle@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Information about the Project/Document**

The Next Generation (NexGen) Risk Assessment project was initiated in 2010 as a multi-year, multi-organization effort to consider new molecular, computational, and systems biology approaches for use in risk assessments. The specific aims of the NexGen effort, described in this draft report, are to: (1) demonstrate proof of concept that the data and methods from recent advances in biology can inform risk assessment; (2) identify which of the information resources and practices are most useful for particular purposes (value of information); (3) develop decision considerations for use of different types of NexGen data and methods to inform different types of assessments; and (4) identify priority research needs.

The “Next Generation Risk Assessment: Incorporation of Recent Advances in Molecular, Computational, and Systems Biology [External Review Draft]” presents the results and lessons learned from the prototypes/case studies for use of molecular, computational, and systems biology data in risk assessment. The prototype results demonstrated proof of concept for an integrated approach to incorporating molecular, computational, and systems biology data in risk assessment and considered various data types for specific assessment purposes. The lessons learned from this project suggested research needs and near- and longer-term implications of incorporating molecular, computational, and systems biology data in risk assessment.

## II. How to Submit Technical Comments to the Docket at [www.regulations.gov](http://www.regulations.gov)

Submit your comments, identified by Docket ID No. **EPA-HQ-ORD-2013-0680**, by one of the following methods:

- [www.regulations.gov](http://www.regulations.gov): Follow the on-line instructions for submitting comments.
- E-mail: [Docket\\_ORD@epa.gov](mailto:Docket_ORD@epa.gov).
- Fax: 202-566-9744.
- Mail: U.S. Environmental Protection Agency, EPA Docket Center (ORD Docket), (Mail Code: 28221T), 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. The phone number is 202-566-1752. If you provide comments by mail, please submit one unbound

original with pages numbered consecutively, and three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

- **Hand Delivery:** The ORD Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue, N.W., Washington, DC. The EPA Docket Center's Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202-566-1744. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by hand delivery, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

*Instructions:* Direct your comments to Docket ID No. **EPA-HQ-ORD-2013-0680**. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked "late," and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through

[www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.regulations.gov) Web site is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA’s public docket visit the EPA Docket Center home page at [www.epa.gov/epahome/dockets.htm](http://www.epa.gov/epahome/dockets.htm).

*Docket:* Documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy.

Publicly available docket materials are available either electronically in [www.regulations.gov](http://www.regulations.gov) or in hard copy at the ORD Docket in the EPA Headquarters Docket Center.

Dated: September 19, 2013.

Debra B. Walsh,  
Acting Director, National Center for Environmental  
Assessment.

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